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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,268	04/11/2006	Alexandra Babarina	14836-49926	1125

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MORRIS MANNING MARTIN LLP
3343 PEACHTREE ROAD, NE
1600 ATLANTA FINANCIAL CENTER
ATLANTA, GA 30326

EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,268	BABARINA ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *4-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending and examined on the merits.

Information Disclosure Statement

Reference 4 of the IDS submitted May 6, 2005, is not in the file. Applicant is invited to provide a replacement copy of said reference for consideration..

Claim Objections

Claims 4-10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot serve as the basis for another multiple dependent claim.. See MPEP § 608.01(n). Accordingly, the claims 4-10 have not been further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Metzger et al (Toxicology, 2001, Vol. 166, pp. 97-108, reference of the IDS submitted May 6, 2005) in view

of Freshney (Culture of Animal Cells, third Edition, 1994, pages 86-87) and Parce et al (Science, 1989, Vol. 246, pp. 243-247).

Claim 1 is drawn to a medium for measuring the efficacy of a tumor therapy on single cell suspensions, comprising the essential amino acids, vitamins, salts and carbon donors, characterized in that the medium comprises from 0.1 to 1 mM buffer of pH 7 to 7.4; 2 to 10 g/l glucose; 2 to 5mM glutamine as a carbon source and 5 to 20% fetal calf serum. Claim 2 embodies the method of claim 1 characterized in that it comprises phosphate buffer as a buffer. Claim 3 embodies the medium of claim 1 or 2, characterized in that it comprises from 8 to 12% fetal calf serum.

Metzger et al teach that malignant cells were grown in RPMI1640 comprising 10% fetal calf serum and 300mg/L glutamine (page 99, lines 13-16 under section 2.2) that tissue samples including tumor tissue were placed in modified RPMI and processed to obtain a single cell suspension (page 100, second column, first full paragraph). Metzger et al teach that cells were then seed into special capsules in order to measure metabolic rate in the presence of chemotherapeutic drugs , and that the RPMI was low-buffered with 1mM phosphate (page 101, first column, lines 4-16). Metzger et al did not teach the exact constituents of the low-buffered PRMI1640 which would include 2 to 10g/l glucose, 2 to 5mM glutamine and 5 to 20% FCS.

Parce et al teaches that reducing the buffer capacity of a growth medium to ~1mM increases the pH change of the medium for a given excretion of acid by the cells and under conditions of a closed system, no drift in pH would be expected to occur due to equilibration with atmospheric CO2 and that metabolic rates are detected by determining acidification rates. Parce et al also teach that normal cell culture medium is used, including serum (page 244, right column, lines 12-28).

Freshney teaches that "normal" RPMI1640 comprises 2g/L glucose and 300 mg/L glutamine which meets the specific limitations of the claims.

It would have been prima facie obvious at the time the claimed invention was made to use "normal" RPMI1640 with 10% FCS with the exception that the only buffer was phosphate buffer at 1mM concentration. One of skill in the art would have been motivated to do so by the teachings of Parce et al on the use of normal growth medium including serum, the teachings of Freshney on the constituents of "normal" RPMI1640 and the teachings of Parce et al suggesting

that only the buffering capacity of the medium should be altered so that said medium is a low buffering medium of 1mM phosphate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643

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